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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,730	05/03/2006	Nicholas Dale	46309-315846	9069
23370 7590 08/27/2010 JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309				
EXAMINER SAKELARIS, SALLY A				
ART UNIT 1797		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/540,730

**Applicant(s)**

DALE ET AL.

**Examiner**

SALLY A. SAKELARIS

**Art Unit**

1797

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-29 and 31-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29 and 31-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/2010 has been entered. Claims 26-29, and 31-55 are pending.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 26-29, 31-44, 47 and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (*Analytica Chimica Acta* 388 (1999) 71-78).

With regard to claim 26, 27, 31, and 50-55, Zhang et al. teach a biological assay device (i.e., biosensor) comprising:

(i) an electrically conductive substrate, wherein the electrically conductive substrate is an electrode (i.e., amperometric hydrogen peroxide biosensor see Page 73, section 2.3 entitled: Preparation of modified electrode); and,

(ii) a layer of sol-gel deposited on at least one surface of the electrically conductive substrate (i.e., Zhang et al. teaches that "MDB was incorporated in sol-gel derived ceramic-carbon composite electrode for electrocatalytic oxidation of NADH" (last 4 lines, left hand column page 72)) in their teaching of a functionalized inorganic-organic composite material derivated by sol-gel for construction of mediated amperometric hydrogen peroxide biosensor.

With regard to claim 26, 27, and claims 50-55, Zhang et al. does not explicitly teach the size of their electrode that is being coated in their biosensor.

Zhang et al. teach that the sol-gel process is highly suitable for the “microencapsulation of a variety of molecules that cannot withstand high temperatures, especially biological active species” (Pg. 71, left column). Furthermore, Zhang teach that it is well known in the art that “the sol-gel derivated silicate matrix can preserve the integrity and directional homogeneity of the protein surface microstructure...so this versatile technique has been extensively applied in the immobilization of enzyme, antigen, and antibody, especially in the biosensor field” (Page 71, right hand side). It should be further noted that while applicant is claiming “microelectrodes” they are further asserting that a “microelectrode” is capable of being characterized by electrodes with millimeter lengths within the dependent claims of claims 50, 51, 53, and 54.

Since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the size of their electrode to one within the scale of 10 $\mu$ m to 10 mm, since such a modification would have involved a mere **change in the size (or dimension) of a component**. A change in size (dimension) is generally recognized as being within the level of ordinary skill in the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). It is well known in the art that the smaller the electrode, the more compact, lighter, and desirable it is and that many design parameters are taken into consideration when determining the size of electrodes for biomedical applications.

With regard to claim 28, while it is maintained that the limitations of a product by process claim are full met by minimally teaching the claimed structure, Zhang et al. teach a device where the sol-gel was obtained through a reaction comprising 3-Mercaptopropyltrimethoxysilane (MPTMS).

With regard to claim 29, a BAS100B/W potentiometer is taught (Pg. 72 right hand side).

With regard to claims 31-35, Zhang teaches that his biosensor is comprised of a biological material such as Horse Radish Peroxidase (HRP) for example, is capable of functioning and being used as claimed.

With regard to claims 36 and 37, Zhang teaches that his biosensor is comprised of a biological material such as Horse Radish Peroxidase (HRP) for example and that sol-gel coating is a versatile technique that has been extensively applied in the immobilization of enzyme, antigen, and antibody, especially in the biosensor field (Page 71, right hand side).

With regard to claims 36 and 37 Zhang does not teach using two or more enzymes in their biosensor.

With regard to claims 36 and 37, addition of a second enzyme to the sensor, would have been obvious to one having ordinary skill in the art at the time the invention was made. Mere **duplication of parts** has no patentable significance unless a new and unexpected result is produced. In re Harza, 124 USPQ 378, 380 (CCPA 1960). Further, it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8. Additional enzymes would have been added to the biosensor of Zhang by a skilled artisan who was motivated to create a biosensor capable of

various different detection methods and applicability. Biosensor capable of detecting various different elements are well known in the art.

With regard to claims 38-44 and 47, Zhang et al. teach their sol-gel was obtained through a reaction comprising silane coupling reagents such as 3-Mercaptopropyltrimethoxysilane (MPTMS) and therefore contains an alkoxysilane and furthermore a MeTMOS (Pg. 72, right side).

2. Claims 45, 46, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Analytica Chimica Acta 388 (1999) 71-78) in view of Collinson et al. (Analytica Chimica Acta 397 (1999) 113-121).

The teachings of Zhang can be seen above.

Zhang does not teach the use of APTEOS as one of their silane coupling agents.

Collinson et al. teach the organic modification of silicates from APTEOS. Among other agents, APTEOS was hydrolyzed and copolymerized and the resultant hybrid sol spin cast on the surface of a glassy carbon electrode (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use agents comprising APTEOS in the creation of a hybrid sol of Zhang's GCE for the expected benefit as taught by Collinson et al. that such films "showed significantly faster ion-exchange relative to films prepared with either TMOS or MTMOS, presumably due to a more open silicate framework"(Abstract).

***Response to Arguments***

Applicant's arguments with respect to claims 26-29, and 31-49 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SALLY A. SAKELARIS whose telephone number is (571)272-6297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sally A Sakelaris/

Examiner, Art Unit 1797

8/26/2010